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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,296	10/16/2003	John T. Kilcoyne	1065-012US03	7920
28863 7590 10/05/2007 SHUMAKER & SIEFFERT, P. A. 1625 RADIO DRIVE SUITE 300 WOODBURY, MN 55125			EXAMINER TOTH, KAREN E	
			ART UNIT 3735	PAPER NUMBER
			MAIL DATE 10/05/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/687,296

Applicant(s)

KILCOYNE ET AL.

Examiner

Karen E. Toth

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-16 and 55-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-16, 55-57 and 59-69 is/are rejected.
- 7) ☒ Claim(s) 58 and 70 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

2. Claims 10, 14-16, 55, 62, and 63 are rejected under 35 U.S.C. 102(e) as being anticipated by Brockway (US Patent 6409674).

Regarding claims 10 and 55, Brockway discloses a monitoring device for monitoring a physiological parameter in a body comprising a housing with a tissue attachment surface (column 8, lines 10-19), a securing structure, such as a pin, that allows the tissue attachment surface to be brought into contact with the tissue at a preselected attachment site when retracted, and that moves through tissue to an extended position (element 312D; column 8, lines 45-55; column 13, lines 43-47; figure 7), and a physiological parameter detector that is carried by the housing (column 8, lines 10-19).

Regarding claim 14, Brockway further discloses the detector comprising a pH detector (column 14 line 61 to column 15 line 4).

Regarding claim 15, Brockway further discloses an RF transmitter (column 7, lines 41-55).

Regarding claim 16, Brockway further discloses an electrical contact for contacting tissue and transmitting data relating to the parameter through the tissue (column 10 line 51 to column 11 line 5).

Regarding claim 62, Brockway further discloses the housing including a docking structure that permits removable attachment of the monitoring device to an instrument that introduces the monitoring device to the preselected attachment site (column 11 line 65 to column 12 line 10).

Regarding claim 63, Brockway further discloses the docking structure comprising a projection (described as a plunger – column 12, lines 11-12), a lumen (element 640), and a recess (described as a cavity – column 12, lines 8-10).

3. Claims 10-13, 56, 57, 59, 60, and 65-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Mills (US Patent 5080663).

Regarding claim 10, Mills discloses a device comprising a housing with a tissue attachment surface (elements 2 and 6); a securing surface that, when retracted, allows the tissue attachment surface to be brought into contact with tissue, and moves to an extended position through the tissue (elements 42, 44, 46, 48); and a physiological parameter detector that is carried by the housing (element 38; column 2, lines 57-61).

Regarding claim 11, Mills further discloses the tissue attachment surface being within a concavity (element 6) on the housing (figure 6).

Regarding claim 12, Mills further discloses the securing structure being bioabsorbable (column 3, lines 8-10).

Regarding claim 13, Mills further discloses a vacuum lumen for drawing tissue into the concavity (column 2, lines 19-30).

Regarding claim 56, Mills further discloses the securing structure extending at least part way across the concavity when extended (figures 6, 7).

Regarding claim 57, Mills further discloses a distal end of the securing structure (element 46) and a blind end in the concavity that can receive the distal end of the securing structure when it is extended (the section labeled as 74 in figure 5, since extending the tag through the skin takes place with needle 26, and both the distal end 46 and the needle 26 remain in the far side of the needle channel – labeled as 74 – when extended, until the needle is retracted).

Regarding claims 59 and 60, Mills further discloses a wall of the housing being transparent so that the interior of the cavity may be viewed (column 2, lines 8-11).

Regarding claim 65, Mills discloses a device comprising a housing (element 2) with a tissue attachment surface inside a concavity (element 6); a securing structure (elements 42, 44, 46, 48); a lumen in connection with the concavity for connection to a vacuum to draw tissue into the concavity (column 2, lines 19-30), and a physiological parameter detector that is carried by the housing (element 38; column 2, lines 57-61).

Regarding claim 66, Mills further discloses that the securing structure, when retracted, allows the tissue attachment surface to contact the tissue, and moves to an extended position through the tissue (figures 6, 7). Though Mills refers to the attachment structure as a “tag”, the structure is equivalent to the broadest definition of the claimed term “pin” and as such, anticipates the claim.

Regarding claim 67, Mills further discloses the securing structure being bioabsorbable (column 3, lines 8-10).

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Regarding claim 68, Mills further discloses the securing structure extending at least part way across the concavity when extended (figures 6, 7).

Regarding claim 69, Mills further discloses a distal end of the securing structure (element 46) and a blind end in the concavity that can receive the distal end of the securing structure when it is extended (the section labeled as 74 in figure 5, since extending the tag through the skin takes place with needle 26, and both the distal end 46 and the needle 26 remain in the far side of the needle channel – labeled as 74 – when extended, until the needle is retracted).

Claim Rejections - 35 USC § 103

4. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mills in view of Bombeck (US Patent 4981470).

Mills discloses all the elements of the claimed invention, as disclosed above, except for the device's predetermined attachment site comprising the esophagus, though Mills does disclose attaching the device in the patient's stomach via the esophagus (column 3 line 67 to column 4 line 1). Bombeck teaches an implantable monitoring device that may be attached to a patient's esophagus (column 3, lines 21-29), in order to monitor conditions in that vicinity. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have attached Mills' device in a patient's esophagus, as taught by Bombeck, in order to monitor conditions in that vicinity.

5. Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway in view of Bombeck.

Brockway discloses all the elements of the claimed invention, as disclosed above, except for the pH detector comprising an antimony electrode. Bombeck teaches a pH sensor comprising an antimony electrode (column 4 lines 51-65). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brockway et al. to include an antimony electrode similar to that of Bombeck, IV in to diagnose gastroesophageal reflux (column 2 lines 46-57).

Response to Arguments

6. Applicant's arguments filed 10 July 2007 have been fully considered but they are not persuasive. Applicant has argued that the expandable securing structure of Brockway is not configured to extend through tissue; the Examiner disagrees, since Brockway clearly shows the cited structure, element 312D, as being expanded within tissue in figure 7.

Allowable Subject Matter

7. Claims 58 and 70 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the structure of claims 58 and 70, including, *inter-alia*, the blind end of the monitoring device's concavity having a locking structure for retaining the securing structure in its extended position.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent Application Publication 2006/0247724 to Gerber, which discloses similar inventions.

US Patent Application Publication 2005/0288555 to Binmoeller, which discloses similar inventions.

US Patent Application Publication 2004/0158125 to Aznoian, which discloses similar inventions.

US Patent 6994712 to Fisher, which discloses similar inventions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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